

EXHIBIT H

Ralph Zipper, M.D.

1 IN THE COURT OF COMMON PLEAS
2 PHILADELPHIA COUNTY
3 TRIAL DIVISION
4 IN RE: PELVIC MESH LITIGATION MAY TERM 2013
5 No. 3913

6 PATRICIA L. HAMMONS,

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8 Plaintiff,

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10 vs.

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12 ETHICON, INC., et al.,

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14 Defendants,

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17 SEPTEMBER 26, 2015

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22 Deposition of RALPH ZIPPER, MD, held at Zipper
23 Urogynecology Associates, 200 South Harbor City
24 Boulevard, Suite 401, Melbourne, Florida, commencing
at 9:52 a.m., on the above date, before
Joan L. Pitt, Registered Merit Reporter, Certified
Realtime Reporter, and Florida Professional
Reporter.

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<p>1 a medical device. 2 A. I'm providing consulting with regard to the 3 design of medical devices, the methods required to use 4 those devices. I'm providing consulting with regard to 5 the labeling of those devices. 6 I am providing consulting with regard to the 7 development of the marketing and advertising materials, 8 the print and advertising, the development of 9 salesforce, salesforce training, professional education. 10 Q. Do you have a written agreement with whatever 11 these companies are? 12 A. Still being negotiated. I'm working in good 13 faith. 14 Q. Does any of this consulting work have to do 15 with treatment devices or medications for the treatment 16 of either stress urinary incontinence or pelvic organ 17 prolapse? 18 MR. THORNBURGH: Objection. 19 A. Yes. 20 Q. Does any of the consulting work have to do with 21 the use of mesh for the treatment of either stress 22 urinary incontinence or pelvic organ prolapse? 23 MR. THORNBURGH: Objection. Current consulting 24 work?</p>	<p>1 Q. As a part of the consulting work that you're 2 doing that we discussed briefly, are you currently 3 involved in any clinical trial related to that treatment 4 of pelvic organ prolapse for the companies for whom 5 you're consulting? 6 A. Can you please better define what you mean by 7 "currently involved in"? 8 Q. Are you designing a clinical trial? 9 A. Yes. 10 Q. Has the clinical trial started enrollment? 11 A. No. 12 Q. So about half an hour before we were supposed 13 to start this deposition I received by e-mail on my 14 iPhone an updated reliance list for you. Okay? 15 I'm going to look at this and talk to you about 16 it. I can't give it to you as an exhibit because I 17 don't have it in a printed form. 18 It indicates in the depositions section 19 Dr. Lackey, Dr. Baker, and Dr. Rohrer, which I believe 20 is the same as the reliance list that's part of 21 Exhibit 1. 22 Have you reviewed any other depositions to 23 prepare to give opinions in this case other than those 24 three?</p>
<p>1 MR. MORIARTY: Yeah, the current consulting 2 work that we're talking about. 3 A. The consulting work requires me to take into 4 consideration the history of the mesh space, including 5 everything from labeling, salesforce training, business 6 modeling, and postmarket surveillance. 7 Q. So it requires you to take all that into 8 consideration, but are they mesh products? 9 A. Can you please rephrase your question? 10 Q. Sure. You said something about your consulting 11 is taking into account the history of the mesh space, 12 things of that nature. 13 What I'm asking specifically is whether the 14 device is a mesh product. 15 MR. THORNBURGH: Objection. 16 A. The device is not a mesh product. 17 Q. Okay. I assume it's an alternative to a mesh 18 product? 19 A. A portion of my consulting work involves the 20 development of a product and the commercialization of a 21 product for the treatment of pelvic organ prolapse. 22 Q. Is there anything else you need to add to the 23 CV that you sent as part of Exhibit 1? 24 A. Not that I'm aware of at this moment.</p>	<p>1 A. Yes. Actually, I had given that information 2 earlier. 3 Q. Tell me what other depositions you've read. 4 A. I have -- it's not related to this case, 5 because my entire experience and training, everything 6 that happens to me in my life, is in consideration. 7 MR. THORNBURGH: What case-specific depositions 8 have you read in this case, is what he's asking. 9 A. Oh, case-specific depositions. Just those 10 three. 11 Q. Okay. Then you have a literature list of 12 about, by my count, and I did this a while ago, it was 13 about 250 articles. Did you read all those? 14 A. At some point in my career, yes. 15 Q. And how was the list assembled? 16 A. Key strokes. 17 Q. What does that mean? 18 A. It means I sat at a computer and I typed out 19 the list. I reviewed the literature, which I do on a 20 weekly basis, or at this time of year, on a daily basis. 21 Also, from time to time I might be reading the 22 expert opinion of defense counsel and looking at their 23 reliance list and realize that there are 10 or 15 great 24 articles on there that I have read in the past I am</p>

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<p style="text-align: right;">Page 14</p> <p>1 relying on.</p> <p>2 When you've been doing this for as long as I 3 have, you've read thousands and thousands of articles, 4 and it's difficult to remember the thousands and 5 thousands of articles that have led to the development 6 of your opinion over the years.</p> <p>7 And the ones that are more current and fresher 8 in the mind quickly get added to the reliance list, but 9 the reliance list continually grows; A, because I'll 10 spontaneously remember articles that I've read that are 11 meaningful and relevant to this case; or because I'll be 12 reminded of them by defense experts who are relying on 13 articles that I've read and they're meaningful and 14 relevant in this case.</p> <p>15 Q. Okay. Just so we're clear, the original 16 reliance list is not necessarily articles that you read 17 just for this case, it's a collective and cumulative 18 experience for you; is that correct?</p> <p>19 MR. THORNBURGH: Objection.</p> <p>20 A. That's correct.</p> <p>21 Q. Okay. New on the reliance list are the reports 22 of Dr. Weber, Julie Drolet, and Joyce Lowman. I assume 23 you read all those three?</p> <p>24 A. Yes, I have.</p>	<p style="text-align: right;">Page 16</p> <p>1 the time you received her report and today?</p> <p>2 A. Not only did I read many of the articles in the 3 Dr. Drolet, Lowman, and Weber reports, but the reading 4 of those articles was not a first reading of those 5 articles. The reliance list of those experts caused me 6 to recollect those articles and go back and look at them 7 again.</p> <p>8 MR. MORIARTY: Okay. What I'd like to do, with 9 Dan and Kila's permission, is when we get a chance 10 today, tomorrow, this week, print this from Kila's 11 e-mail, or your assistant's e-mail, and just reserve 12 an exhibit for it. Is that acceptable?</p> <p>13 MR. THORNBURGH: Yeah, that's fine.</p> <p>14 MR. MORIARTY: Okay.</p> <p>15 MS. SUTHERLAND: Nobody has it already printed, 16 do you want to ask that?</p> <p>17 MR. MORIARTY: You didn't print it, did you?</p> <p>18 MR. THORNBURGH: I don't have it printed, so I 19 don't think we have any extras, no, but we'll get it 20 for you probably today.</p> <p>21 MR. MORIARTY: It's 41 pages long, so we can 22 wait until the weekday.</p> <p>23 BY MR. MORIARTY:</p> <p>24 Q. Now, Doctor, after reviewing the reliance list,</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. And then you added to the reliance list 2 citations from the report of Anne Weber, did you not?</p> <p>3 A. Yes, I did.</p> <p>4 Q. And it looks like some of those are company 5 documents; correct?</p> <p>6 A. This is correct.</p> <p>7 Q. Then medical literature from the report of 8 Julie Drolet, and there is a long list, which I've not 9 had an opportunity to count, but you did add some things 10 from Dr. Drolet's literature list; correct?</p> <p>11 A. As I referenced a few moments ago, 12 Mr. Moriarty, when I read through the opinions of 13 defense counsel's experts, it often causes me to realize 14 that those are articles that I have read in the past 15 that I have considered in my opinion, and they have been 16 added to my reliance list.</p> <p>17 Q. Okay. Do you know how many of these you 18 specifically read between the time you got Dr. Drolet's 19 report and today?</p> <p>20 A. Many.</p> <p>21 Q. And then you did the same thing for the 22 literature list of Dr. Lowman; is that correct?</p> <p>23 A. This is correct.</p> <p>24 Q. And did you read some of these articles between</p>	<p style="text-align: right;">Page 17</p> <p>1 you drafted a report that is part of Exhibit 1; is that 2 correct?</p> <p>3 MR. THORNBURGH: Objection.</p> <p>4 Q. I'm sorry. After reading whatever you felt was 5 appropriate to prepare for opinions in this case, you 6 drafted the report that's Exhibit 1; correct?</p> <p>7 A. The report that is Exhibit 1 is based on my 8 review of the medical records of Mrs. Hammons, my 9 knowledge, training, and experience over the last 20 10 some years, which includes my extensive reading of the 11 medical literature, and my reliance list.</p> <p>12 Q. And then at some point later you drafted this 13 supplemental report dated September 17, 2015; correct?</p> <p>14 A. That's correct.</p> <p>15 (Zipper Exhibit No. 7 was marked for 16 identification.)</p> <p>17 BY MR. MORIARTY:</p> <p>18 Q. And this is just a one-paragraph letter talking 19 about the medical bills from Dr. Lackey and Dr. Heit 20 being reasonably -- reasonable and medically necessary; 21 correct?</p> <p>22 A. This is correct.</p> <p>23 Q. Is there any place in your Exhibit 1, your 24 report, in which you gave an opinion that Mrs. Hanson's</p>

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<p>1 I do not consider it appropriate to really assess this 2 dyspareunia until the healing process is substantially 3 completed itself.</p> <p>4 So I would expect anybody to have sensitivity 5 over an incision, whether it be on their abdomen, their 6 knee, or their elbow, or their vagina, in the first 7 several months following surgery. But given time for 8 appropriate healing, my guesstimate on my native 9 tissue-related dyspareunia rate is in the 2 to 4 percent 10 range.</p> <p>11 Q. Okay. Now, originally on your reliance list 12 there were no Ethicon company documents. Your updated 13 reliance list has some. Do you know when you reviewed, 14 received and reviewed, those documents?</p> <p>15 A. No, I do not. I couldn't tell you which. 16 There were perhaps one or two that are more recent, but 17 I could not tell you when I first reviewed them.</p> <p>18 However, having looked at the opinions of the 19 other experts, it caused me to dig a little bit into the 20 Corvela database, and upon digging a little bit into the 21 Corvela database, I found additional information that I 22 considered important and relevant to my case-specific 23 opinion.</p> <p>24 Q. Okay. Of the patients in whom you performed</p>	<p>1 rare occasion, if someone expressed interest in my data, 2 other than that, I've not endeavored to publish.</p> <p>3 Q. How many times do you believe you used Prolift, 4 either anterior, posterior, or total?</p> <p>5 A. I can say with rather vivid memory and a high 6 agree of confidence that my use of Prolift was limited 7 and short-lived secondary to my dissatisfaction with the 8 product.</p> <p>9 Q. Can you tell me when you used it?</p> <p>10 A. No. Shortly after it came to market.</p> <p>11 Q. How many patients do you think you implanted 12 with Prolift?</p> <p>13 A. My guesstimation is, and, once again, this is a 14 guesstimation, but my frustration with the design of the 15 product and the defective nature of the product caused 16 me to discontinue use of the product certainly after 17 less than 10 uses, although I have explanted most likely 18 over 100 pieces of Prolift for complications such as 19 pain, erosion, and dyspareunia.</p> <p>20 Q. I'm sorry. What was that number?</p> <p>21 A. Over 100 pieces of Prolift explanted for 22 complications such as pain, erosion, and dyspareunia.</p> <p>23 Q. How many explants do you believe you have done 24 overall for mesh used for pelvic organ prolapse repair?</p>
<p style="text-align: center;">Page 103</p> <p>1 transvaginal mesh repairs for pelvic organ prolapse, do 2 you have any estimate from the number of those patients 3 who have suffered clinical signs and symptoms of 4 contraction?</p> <p>5 MR. THORNBURGH: Objection. Asked and 6 answered.</p> <p>7 MR. MORIARTY: No, I asked about erosion and 8 dyspareunia. I haven't asked about contraction.</p> <p>9 MR. THORNBURGH: I think they're interrelated.</p> <p>10 A. My findings are, for clinical signs and 11 symptoms for contraction, approximately 15 percent for 12 self-tailored mesh and approximately 90 percent for 13 armed mesh, which I believe is consistent with the 14 findings of Velemir, who evaluated contraction with 15 Prolift.</p> <p>16 Q. Now, I've asked you about your experience with 17 all these different procedures and complications and 18 whatnot. Other than the poster presentation that I 19 marked and that we discussed earlier, have you published 20 the results of your experience with these procedures in 21 any peer-reviewed medical literature?</p> <p>22 A. No. I consider myself more of a clinician and 23 my life and my career has been dedicated to the 24 treatment of patients and not to the publication. On</p>	<p style="text-align: center;">Page 105</p> <p>1 A. Hundreds, including Prolift last week.</p> <p>2 Q. So you've explanted hundreds of transvaginal 3 meshes used for pelvic organ prolapse repair and some 4 subset of that has been Prolift?</p> <p>5 A. I've explanted hundreds of pieces of Prolift 6 mesh for both erosion, severe chronic pain, and 7 dyspareunia.</p> <p>8 Q. Now, when you say "explanted" and you mentioned 9 "erosion," are you talking about --</p> <p>10 A. Symptomatic erosions.</p> <p>11 Q. Are you talking about just a small -- the small 12 eroded area or a wider explant of the mesh?</p> <p>13 A. I do what I feel is necessary to treat the 14 patient based on their symptoms and physical findings. 15 Typically it's a wider explantation.</p> <p>16 The patient I -- Prolift patient I treated just 17 last week had been suffering with severe, debilitating, 18 chronic pelvic pain, had failed multiple surgeries 19 elsewhere. Nobody was able to help her. And I did a 20 very large wide dissection and was able to remove her 21 proximal Prolift arms down to the level of the 22 sacrospinous ligament, and she -- after years and years 23 of suffering and pain, she's achieved 25 to 50 percent 24 improvement.</p>